EXHIBIT A

United States ex rel. Penelow, et al. v. Janssen Products, LP, Civ. Action No. 12-7758(MAS)(LHG), D.N.J.

Report of Kenneth W. Schafermeyer, Ph.D.
January 31, 2020

1. Introduction

1. I am a Professor of Pharmacy Administration and Director of the Office of International Programs at the St. Louis College of Pharmacy. In a previous role at the College I served as the Director of Graduate Studies and headed a Master's degree program in Managed Care Pharmacy. Since my licensure as a pharmacist in 1976, I have worked with, taught about, and analyzed the operations of pharmacies, their financial performance, their costs of dispensing, and their reimbursement by private and public prescription programs, including government-supported health care programs such as Medicare, Medicaid, TRICARE, and the Federal Employees Health Benefits Program. I have worked in an advisory role for pharmacy benefit managers and state Medicaid programs, including service as Chair of the Missouri Medicaid Prior Authorization Task Force. I have also worked with and taught about the operations of managed care organizations and pharmacy benefit managers (PBMs). I have been designated as a Fellow of the Academy of Managed Care Pharmacy and as a Fellow of the American Pharmacists Association. Through my education and experience, I have personal knowledge of the practices of pharmaceutical manufacturers, pharmacy benefit managers, state and federal healthcare programs, third-party insurance payers and pharmacies as they relate to the purchasing, pricing, dispensing, and reimbursement of prescription drugs. My *curriculum vita* (Exhibit A) contains a list of the cases in which I have testified within the last five years.

2. Of relevance to my report, Plaintiffs in this case allege that Defendant Janssen illegally promoted off-label and/or medically unnecessary use of two antiretroviral drugs – Prezista (darunavir) and Intelence (etravirine) – and that such promotion was a substantial factor in causing physicians to write off-label prescriptions subsequently reimbursed under Medicare Part D and various states' Medicaid programs, among other payers.

3. I have been retained by the Plaintiffs to provide a rebuttal to the report submitted by Defendant's expert witness, Dr. Babette Edgar, with regard to "the statutory and regulatory framework for Medicare Part D … CMS policies and practices regarding the Medicare reimbursement for antiretroviral medications used to treat HIV, and … the scope of Medicare Part D coverage of, and reimbursement for antiretroviral medications."[1]

4. My report is based on my knowledge of the industry, professional experience, review of relevant industry publications, government statutes, regulations, rules, guidance and relevant case law and pleadings as well as documents provided to me by counsel. A list of the materials I relied upon in forming my opinions are attached as Exhibit B. I am compensated at the rate of $600 per hour for research, review, preparation, and testimony. I reserve the right to amend or update my opinions based on any information that may become available to me or known by me in the future.

[1] Edgar Report, paragraph 7

5. The remainder of this report is divided into two main sections. The first section addresses relevant issues pertaining to Medicare Part D, including administration of the drug benefit, funding sources, drug coverage and utilization management tools. The second section addresses the financial implications of the Defendant's alleged behavior on Medicare Part D for promoting Prezista and Intelence for off-label and/or medically unnecessary use.

2. Medicare Part D

2.A. Background

6. Medicare Part D was established pursuant to the Medicare Prescription Drug Benefit, Improvement, and Modernization Act of 2003 (MMA) effective January 1, 2006. Medicare Part D provides subsidized coverage for prescription drugs to eligible beneficiaries voluntarily enrolled through qualified insurance providers referred to as "sponsors."[2] These eligible beneficiaries must first sign up for Medicare Parts A and B. Sponsors are reimbursed by the Federal Government through the Centers for Medicare and Medicaid Services (CMS), a federal agency and branch of the U.S. Department of Health & Human Services that administers Medicare and Medicaid. CMS requires that sponsors develop networks of participating pharmacies to dispense medications to beneficiaries.[3] Sponsors generally contract with PBMs to establish these networks, process claims and perform other administrative duties.

7. Part D beneficiaries pay premiums for prescription drug coverage that are lower than what would be available without a federal subsidy. Other sources of funding for Part D include patient cost sharing (deductibles, copayments, or coinsurance), contributions from the general fund of the U.S. Treasury, and payments from states, which must offset some of the cost of prescription drugs for Medicaid beneficiaries who also are enrolled in Medicare.[4,5,6]

8. All Medicare Part D Plans must be authorized by CMS. As long as their designs are at least actuarially equivalent or better than the standard plan design, prescription drug plans are

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[2] 42 C.F.R. § 423

[3] 42 C.F.R. § 423.120(a)

[4] Centers for Medicare and Medicaid Services. (2016). Brief summaries of Medicare and Medicaid. Baltimore, MD: U.S. Department of Health and Human Services. Retrieved from https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/Downloads/MedicareMedicaidSummaries2016.pdf.

[5] Henry J. Kaiser Family Foundation. (2005a). *Medicare Chart Book 2005*. Menlo Park, CA: Henry J. Kaiser Family Foundation

[6] Henry J. Kaiser Family Foundation (2015a). *Medicare Advantage*, June 29, 2015. Menlo Park, CA: Henry J. Kaiser Family Foundation. Retrieved from http://kff.org/medicare/fact-sheet/medicare-advantage/. [51] 42 *CFR* § 423.104(d)

given the flexibility to offer alternative benefit designs.[7] Taken in total, Part D is designed for the Federal Government, on average, to pay at least 74.5% of all covered Part D drug spending. The 74.5% total is established by federal law.[8]

2.B. Part D expenditures

9. While CMS gives sponsors latitude in benefit design, it specifies a Defined Standard Benefit, which originally included:

   (1) An annual deductible in which beneficiaries paid 100% of the first $250 of drug costs.

   (2) An initial coverage period in which beneficiaries paid 25% of drug costs up to the initial coverage limit of $2,000; the plan paid the other 75%. In other words, for the first $2,250 of drug costs, the beneficiary paid $750, and the plan paid $1,500.

   (3) A coverage gap (or "donut hole") in which beneficiaries fell into a second 100% deductible phase until they incurred a total of $3,600 in true-out-of-pocket (TrOOP) costs.

   (4) A catastrophic coverage phase for beneficiaries exceeding a total of $3,600 in out-of-pocket costs. Beyond this point, costs were split three ways with the government reinsurance covering approximately 80%, the plan covering approximately 15%, and the patient covering either a 5% coinsurance or a copayment of $5 for brand-name drugs or $2 for generics.

10. The annual deductible, benefit limits, and catastrophic threshold were indexed to rise with Part D spending.[9,10] The Patient Protection and Affordable Care Act enacted in March 2010 brought important changes to the Part D drug benefit. This healthcare reform law provided for a $250 rebate to Part D enrollees to cover spending in the donut hole during 2010. Additional subsidies in the coverage gap were then phased in for generic drugs beginning in 2011 and for brand-name drugs beginning in 2013, eventually reducing the coinsurance rate in that gap from 100% to 25% by 2020. Table 1 illustrates Standard Benefit parameters for the relevant period (2006-2014) and Table 2 illustrates the donut hole coinsurance rates for this same period.

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[7] 43 C.F.R. § 423.104(e)

[8] 42 U.S.C § 1395w-115

[9] Henry J. Kaiser Family Foundation (2015b). *The Medicare Part D Prescription Drug Benefi*t. Menlo Park, CA: Henry J. Kaiser Family Foundation. Retrieved from http://kff.org/medicare/fact-sheet/the-medicareprescription-drug-benefit-fact-sheet/

[10] 42 U.S.C. § 1395w-115.

Table 1
Medicare Part D Standard Benefit Model Plan Parameters 2006-2014

	2014	2013	2012	2011	2010	2009	2008	2007	2006
Deductible – After the Deductible is met, beneficiary pays 25% of covered costs up to total prescription costs meeting the Initial Coverage Limit.	$310	$325	$320	$310	$310	$295	$275	$265	$250
Initial Coverage Limit – Coverage Gap (Donut Hole) begins at this point. (Beneficiary pays 100% of their prescription costs up to the Out-of-Pocket Threshold.)	$2,850	$2,970	$2,930	$2,840	$2,830	$2,700	$2,510	$2,400	$2,250
Out-of-Pocket Threshold – This is the Total Out-of-Pocket Costs including the Donut Hole.	$4,550	$4,750	$4,700	$4,550	$4,550	$4,350	$4,050	$3,850	$3,600
Total Covered Part D Drug Out-of-Pocket Spending Including the Coverage Gap – Catastrophic Coverage starts after this point.	$6,455	$6,734	$6,658	$6,448	$6,440 (plus $250 rebate)	$6,154	$5,726	$5,451	$5,100
Copayments during catastrophic coverage phase									
Preferred multi-source drugs	$2.55	$2.65	$2.60	$2.50	$2.50	$2.40	$2.25	$2.15	$2.00
Other drugs	$6.35	$6.60	$6.50	$6.30	$6.30	$6.00	$5.60	$5.35	$5.00

Source: https://q1medicare.com/PartD-The-MedicarePartDOutlookAllYears.php

Table 2
Medicare Part D Donut Hole Coinsurance Rates 2006-2014

	Generic Drugs		Brand-Name Drugs			
Plan Year	Beneficiary Pays (Amount that counts toward TrOOP)	Plan Pays	Beneficiary Pays	Amount that Counts Toward TrOOP	Plan Pays	Drug Manufacturer Discount
2006-10	100%	0%	100%	100%	0%	0%
2011	93%	7%	50%	100%	0%	50%
2012	86%	14%	50%	100%	0%	50%
2013	79%	21%	47.5%	97.5%	2.5%	50%
2014	72%	28%	47.5%	97.5%	2.5%	50%

Source: https://q1medicare.com/PartD-MedicarePartD_DonutHole_Discount.php

11. In 2012, 28% of Part D spending was incurred in the coverage gap phase and 48% was

incurred in the catastrophic coverage phase.[11] After the catastrophic coverage phase starts, beneficiaries pay 5% coinsurance, plans pay 15% and government reinsurance covers the remaining 80%.

12. Part D has a complex payment structure. Rather than reimbursing on a fee-for-service basis as is generally done in Medicare Parts A and B, Medicaid, and many private-pay plans, Medicare Part D requires risk sharing and payments made on both a prospective and retrospective basis. There are three types of prospective payments from the federal government (made through CMS/Medicare) to the private Medicare Part D Plan sponsors:

Direct Subsidy. Plan sponsors submit bids that are used in determining a monthly capitation payment – a per-member per-month payment to the sponsor. The direct subsidy is modified by case mix and premium payments. Direct subsidy payments are not adjusted during the plan year, even as actual drug costs change. CMS reviews actual enrollment levels and risk scores to reconcile direct subsidy payments, and those direct subsidy payments are also taken into account in the risk corridor adjustments.[12]

(1) Low-Income Subsidy (LIS). Medicare provides a variety of subsidies for low-income beneficiaries who enroll in Part D. For example, individuals with both Medicare and Medicaid ("dual eligibles") pay no monthly premium or deductible, and their copayments for prescription drugs are fairly nominal and vary according to income, with copayments for generic drugs being less than for brand-name drugs. Numerous other groups of Medicare beneficiaries with limited incomes and resources also qualify for some type of assistance with Part D premiums, deductibles, and copayments.[13] CMS makes prospective payments to sponsors for estimated premiums and cost sharing for certain low-income enrollees and later reconciles prospective payments with actual expenditures.

(2) Reinsurance Subsidy. Beneficiaries who exceed the TrOOP cost limits are covered in the catastrophic coverage phase in which CMS covers 80% of costs. CMS makes prospective payments to sponsors based on estimated costs and then later reconciles prospective payments with actual expenditures.

13. In addition to these three types of prospective subsidy payments, there are retrospective

[11] MedPAC, *Report to the Congress: Medicare and the Health Care Delivery System* (June 2015) pp. 144-5. Found at: http://www.medpac.gov/docs/default-source/reports/chapter-6-sharing-risk-in-medicare-part-d-june-2015-report-.pdf

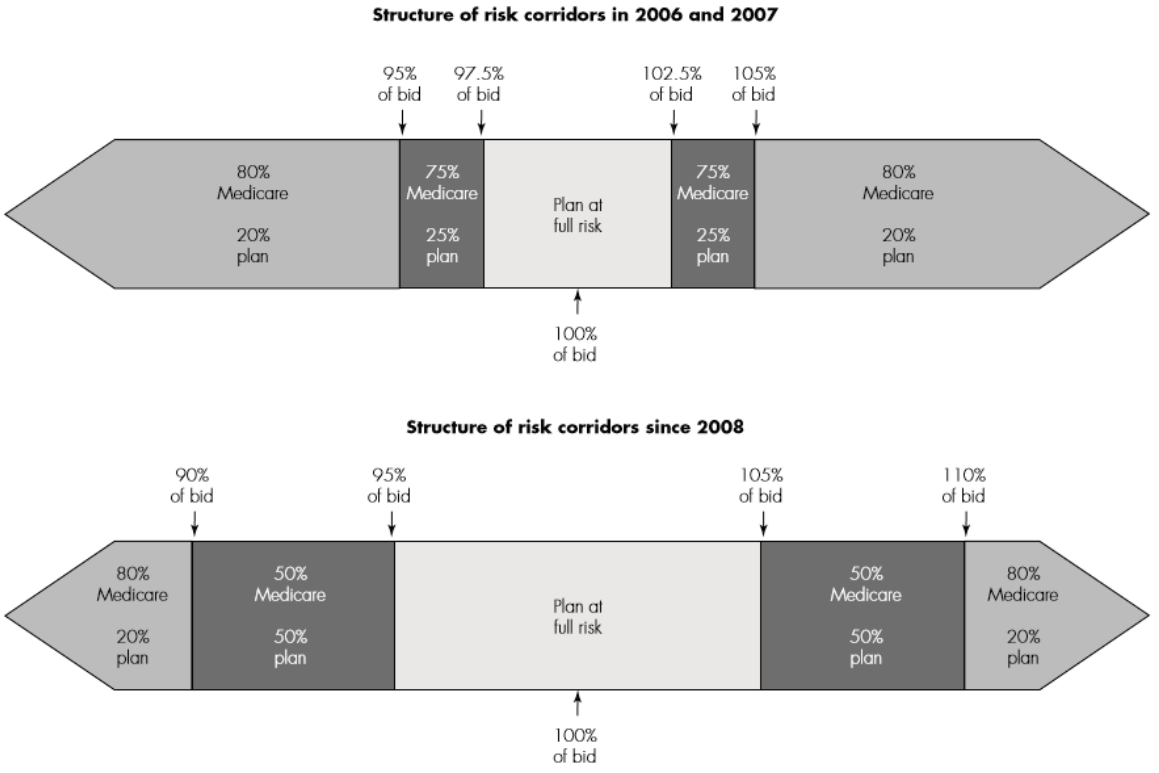
[12] *Id.* p. 152

[13] Henry J. Kaiser Family Foundation. (2009b). *Low-Income Assistance under the Medicare Drug Benefit*. Menlo Park, CA: Henry J. Kaiser Family Foundation. Retrieved from https://www kff.org/medicare/fact-sheet/low-income-assistance-under-the-medicare-drug/

risk-sharing adjustments made by CMS to the Part D Plan sponsors to reconcile low-income and reinsurance subsidy payments.[14] CMS establishes "risk corridors" that limit sponsors' unexpected profits or losses that are determined by a retrospective comparison of sponsors' actual claims experience with their original bids. For the first two years of the program (2006-07), sponsors took full risk for expenditures 2.5% above or below their bids. In other words, the sponsor kept all the profit or incurred all the losses within this range.

14. Since 2008, retrospective risk corridor payments have been zero if sponsors' costs are within 5% above or below their bids. If a sponsor's actual expenses are between 90 and 95% of its bid, the excess profits are shared equally between the sponsor and CMS. If the sponsor's actual costs are less than 90% of its bid, it keeps 20% of this amount and CMS gets 80%. Conversely, if a sponsor's costs are between 105 and 110% of its bid, the sponsor and CMS share the loss equally. If expenses are more than 110% of its bid, the sponsor incurs 20% of the loss and recoups the remaining 80% from CMS.

Figure 1



Source: MedPAC, Report to the Congress: Medicare and the Health Care Delivery System (June 2015) Figure 6-3, p. 147. Found at: http://www.medpac.gov/docs/default-source/reports/chapter-6-sharing-risk-in-medicare-part-d-june-2015-report-.pdf

[14] *CMS Instructions: Requirements for Submitting PDE Data* (June 2005), p. 6. Found at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/DrugCoverageClaimsData/Downloads/PDEInstruction_062305.pdf

15. Part D plans transmit to CMS a Prescription Drug Event (PDE) record for each covered prescription dispensed. The PDE record includes over thirty fields including name, strength, and dosage form of the drug, the number of units dispensed, days' supply, amount paid to the pharmacy, etc. The PDE record does not include the patient's diagnosis, the indication for which the prescription was dispensed or the directions to the patient.[15]

16. After the end of the benefit year, CMS uses PDE data to reconcile low-income subsidy (LIS), reinsurance subsidies and risk corridor payments with Part D plans.

17. A further adjustment is made to reflect what is known as "direct and indirect remuneration" (DIR) – additional compensation received by the PBM after the point-of-sale that changes the final drug cost to the payer. Examples of compensation are manufacturer rebates and concessions paid by pharmacies based on performance metrics. DIR fees are considered in plans' bids and then factored into CMS's calculation of final payments to Part D plans. Since DIR adjustments are applied post point-of-sale, they do not lower patients' cost sharing. For expensive drugs, such as ARVs, rebates can significantly lower the final cost to CMS, but not to patients, who then incur higher TrOOP and more quickly reach the catastrophic coverage phase where CMS pays 80% of the cost. The use of rebates, as opposed to more straight-forward price discounts, effectively increases CMS reinsurance expenditures.[16]

2.C. Formularies

18. Each Part D plan establishes a formulary, which generally includes at least two drug products from each therapeutic class.[17] CMS also established six "protected classes" that requires substantially all FDA-approved drugs within these classes to be covered. One of these classes is antiretrovirals (ARVs), which includes Prezista and Intelence.[18]

    Edgar opines that, since Prezista and Intelence belonged to a "protected class" of antiretrovirals, "a Part D sponsor would not have denied coverage for either Prezista or Intelence, and coverage for these drugs was unimpeded under Medicare Part D during all relevant times."[19] This is not consistent with my understanding – the fact that a drug is

[15] *CMS Instructions: Requirements for Submitting PDE Data* (2006), pp. 11-17.

[16] CMS.gov, "Medicare Part D – Direct and Indirect Remuneration (DIR)" (January 19, 2017). Found at: https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir

[17] C.F.R. § 423.120(b)(2)(i)

[18] *Medicare Prescription Drug Benefit Manual*, ch. 6 § 30.2.5

[19] Edgar Report, paragraphs 11-12. Edgar repeats this same argument in paragraphs 22-26.

required to be on formulary does not mean that it is required to be covered for *any* conceivable use. It would be too far of a stretch to conclude that federal policies facilitating access to HIV/AIDS medications means that CMS does not care at all about their off-label use.

19. Edgar states that Medicare Part D formularies typically do not require prior authorization (PA) for Prezista or Intelence. Although the Medicare Prescription Drug Benefit Manual indicates that PA and step therapy are not often applied to HIV/AIDS drugs, the only specifical prohibitions are for "PA or ST requirements that are intended to steer beneficiaries to preferred alternatives within these classes for enrollees who are currently taking a drug." In fact, the Manual does state that "Part D sponsors should consistently utilize PA for those drugs with the highest likelihood of non-Part D covered uses [such as] [h]igh likelihood of use for non-medically accepted indications…." It should also be pointed out that a policy to allow for increased access to a certain class of drugs does not mean that CMS is indifferent to their off-label use. Although using a policy like a prior authorization can help decrease improper off-label use, it can also adversely raise barriers for access. Drawing the balance in favor of access does not mean that the concerns about off-label use or reimbursement for off-label use are nonexistent, or that CMS is disinterested in controlling unsafe use of these products. In fact, eschewing a PA requirement to streamline access means that CMS must rely even more heavily on physicians to prescribe properly, which is undermined when companies improperly promote off-label use.

2.D. Utilization management tools

20. Whether a given drug product is on formulary or not is not the only consideration when determining coverage. As described herein, there are restrictions for promotion of off-label use and requirements that drug products must be prescribed for medically approved indications and be medically necessary and reasonable.[20]

21. CMS recognizes the need to control unsafe use of drugs by allowing utilization management tools, even for protected classes.[21] CMS allows Part D sponsors to employ utilization management tools, such as quantity limits (i.e., a limit on the amount of a drug that may be covered over a period of time), step therapy (i.e., prescribing guidelines requiring specified preferred drugs be tried before "second line" products in that therapeutic class can be prescribed), and prior authorization (PA) in which the plan must give permission to use a specific product after collecting data from prescribers that justify

[20] I am aware that Part D plans have some discretion to permit coverage of additional drugs through individual coverage appeals. I have been instructed by counsel to disregard those instances because those situations were not in play in this litigation.

[21] *Medicare Prescription Drug Benefit Manual*, ch. 6 § 30.2

the use of the product. While these utilization management tools are designed to set limits on use of certain drug products, this goal must be balanced with clinical considerations regarding the need to promote access and assure continuity of care.[22]

22. Additionally, Medicare Part D's quality assurance regulations *require* plans to have a quality assurance system to "reduce medication errors and adverse drug interactions and improve medication use" by, among other things: (1) "concurrent drug utilization review programs [to review] *incorrect drug dosage* or duration of therapy" and (2) prospective drug utilization review "…in order to identify patterns of *inappropriate or medically unnecessary care* among enrollees."[23] (Emphasis added.)

23. Part D plans also establish "medication therapy management programs…to ensure that Part D drugs…*are appropriately used* to optimize therapeutic outcomes through improved medication use."[24] (Emphasis added.)

24. Clearly, Edgar's assertion that coverage for Prezista and Intelence "was unimpeded under Medicare Part D during all relevant times"[25] is an overstatement. Whether use of these drugs was limited by formulary restrictions, CMS obviously cares about ensuring proper dosage, appropriate use to optimize therapeutic outcomes, and medically necessary and reasonable use.

3. Financial impact of Defendants' conduct on Medicare Part D

25. Edgar attempts to minimize the financial impact that non-reimbursable drug utilization (i.e., utilization resulting from off-label or not medically necessary and reasonable promotions) has on Part D expenditures.[26] Her analysis is inaccurate in at least two respects. First, the bulk of the federal payments for Part D are, in fact, impacted by the number and cost of prescription claims. Second, the fact that CMS pays Part D programs in part on a prospective basis does not mean federal payments are not impacted by fraudulent claims for reimbursement.

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[22] *Medicare Prescription Drug Benefit Manual*, ch. 6 § 30.2.2.1

[23] 42 C.F.R. § 423.153(c)

[24] 42 C.F.R. § 423.153(d)

[25] Edgar Report, paragraphs 11-12. Edgar repeats this same argument in paragraphs 22-26.

[26] "[U]nder Part D, CMS does not review and reimburse for outpatient prescription drug claims on a prescription-by-prescription basis. Instead, CMS pays prospective subsidies to a Part D sponsor based on its projected annual cost of administering the Part D benefit and, at the end of the year, conducts an annual reconciliation to determine whether the prospective subsidies the Part D sponsor received were significantly above or below its actual covered Part D drug costs." Edgar Report, paragraph 10.

3.A. CMS payment on a prospective basis does not negate the financial impact of off-label prescriptions

26. As outlined in Section 2.B of this report, federal payments for drugs under Part D are made through a number of different payment streams, including the direct subsidy, the low-income subsidy (LIS), reinsurance and risk corridor payments. Edgar focuses almost exclusively on the direct subsidy, and makes only passing reference to the low-income subsidy and the reinsurance subsidy.[27] In fact, Table 3 illustrates that when comparing the amount of reimbursement through direct subsidies to amounts paid through LIS and reinsurance subsidies during the period 2007-2014, the direct subsidy represented only about a third of these Part D payments (35.4%).[28]

Table 3
Part D Reimbursements for Direct Subsidy, Reinsurance and LIS (in Billions)

Calendar Year	Direct Subsidy	Reinsurance	Low-Income Subsidy	Total
2007	$18.1	$8.0	$16.7	$42.8
2008	$17.7	$9.4	$18.1	$45.2
2009	$18.9	$10.1	$19.6	$48.6
2010	$19.7	$11.2	$21.1	$52.0
2011	$20.1	$13.7	$22.2	$56.0
2012	$20.8	$15.5	$22.5	$58.8
2013	$20.3	$19.2	$23.2	$62.7
2014	$18.6	$27.2	$24.3	$70.1
Total 2007-14	$154.2	$114.3	$167.7	$436.2
Percentage	35.4%	26.2%	38.4%	100.0%

27. As outlined above, the federal payments under the LIS and reinsurance streams are largely prospective, but the reconciliation between CMS and the plan is made based on actual expenditures. In other words, in the end, CMS is, indeed, directly impacted by the actual cost for prescriptions that were not appropriate for reimbursement.

28. Accordingly, for well more than half of the amount of federal reimbursements under Part D, there is a direct financial link between claims that are not reimbursable (i.e., for off-label or medically unnecessary uses) and the amounts paid out by CMS.

[27] Edgar Report, paragraphs 40-41 and footnote 6.

[28] *Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplemental Medical Insurance Trust Funds* (2017), p. 146.

29. Further, even under the direct subsidy payments that are not reconciled to exact expenditures, a plan's future bids regarding anticipated costs are based on actual experience from prior years. As explained, the risk corridor adjustments turn on how close a plan sponsor's predicted costs in the bid came to the actual costs incurred during the term of the bid.

30. Edgar states that unlike in Medicare Parts A and B, "CMS pays prospective subsidies to a Part D sponsor based on its projected annual cost of administering the Part D benefit and, at the end of the year, conducts an annual reconciliation to determine whether the prospective subsidies the Part D sponsor received were significantly above or below its actual covered Part D drug costs."[29] She subsequently notes that "government payment under Medicare Part D is not on a prescription-by-prescription basis,"[30] and then segues into a discussion about the annual reconciliation and the fact that no reconciliation will occur if the prospective subsidies "were not significantly above or below actual covered drug costs."[31]

31. It is not entirely clear what Edgar is attempting to convey by this discussion, but the implication seems to be that Medicare Part D is not directly impacted by any particular prescription (even if off-label) because the prescriptions are not individually paid but are essentially pre-paid through the prospective subsidies.

32. The fact that payments are made on a prospective basis does not mean that CMS is not impacted by fraudulent prescription drug claims. The prospective nature of some of the payments is largely a matter of timing and logistics, subject to end-of-year reconciliation of some type.

33. Additionally, Edgar seems to suggest that even if CMS were to detect "erroneous" claims (i.e., prescription claims that are inaccurate or inconsistent with Medicare Part D requirements), such errors "[do] not…change the direct subsidy."[32] This statement omits some important details. First, as described above, the direct subsidy only represents a comparatively small portion of Part D reimbursement. Second, erroneous prescriptions can affect the amount of TrOOP, the amounts paid in the catastrophic coverage phase, low-income subsidy payments, reconciliations and the amounts of sponsor's future bids. Furthermore, if it were able to detect these erroneous prescriptions, CMS would have been able to demand post-point-of-sale (POS) claims adjustments for these claims.[33] Contrary to

[29] Edgar Report, paragraph 10

[30] Edgar Report, paragraph 39

[31] Edgar Report, paragraph 41

[32] Edgar Report, paragraph 42

[33] Cheri Rice, Director, Medicare Plan Payment Group memo to Part D Plan Sponsors, July 3, 2013.

Edgar's implication, CMS is, indeed, financially impacted by off-label marketing that leads to submission of non-reimbursable prescription claims.

3.B. CMS reimbursement for prescriptions that are off-label or not medically necessary and reasonable

34. Drugs covered by Medicare Part D include FDA-approved prescription drugs written for medically approved indications.[34] Medically approved indications are uses approved by FDA or supported by approved compendia such as *American Hospital Formulary Service Drug Information* or *DRUGDEX® Information System*.[35] As described herein, however, and as the court has already concluded in this action,[36] the medically approved indications for a drug are not the only considerations for Medicare Part D coverage.

35. The initial 2008 FDA-approved labeling for Intelence limits "indications and usage" to the following:

> *INTELENCE® is a human immunodeficiency virus type 1 (HIV-1) specific, non-nucleoside reverse transcriptase inhibitor (NNRTI) indicated:*
>
> - *In combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment-experienced adult patients, who have evidence of viral replication and HIV-1 strains resistant to an NNRTI and other antiretroviral agents.*[37]

36. In March 2012, the indication listed in the FDA-approved label for Intelence was revised to expand use for treatment-experienced patients 6 years of age and older:

> *"INTELENCE® is a human immunodeficiency virus type 1 (HIV-1) non-nucleoside reverse transcriptase inhibitor (NNRTI) indicated for treatment of HIV-1 infection in treatment-experienced patients 6 years of age and older with viral strains resistant to an NNRTI and other antiretroviral agents."*[38]

37. The 2010 the *American Hospital Formulary Service Drug Information* (*AHFS)* documented entry for Intelence specifies "uses" as:

> "*Etravirine is used in conjunction with other antiretroviral agents for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in treatment-experienced*

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[34] 42 U.S.C § 1395w-102(e)(1)

[35] *Medicare Prescription Drug Benefit Manual*, ch. 6 § 10.6

[36] *United States v. Johnson & Johnson,* 2017 WL 2367050 at *5 (D.N.J., May 31, 2017)

[37] Prescribing information for Intelence: https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/022187lbl.pdf

[38] Prescribing information for Intelence: https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/022187s009lbl.pdf

(previously treated) adults who have evidence of ongoing HIV-1 viral replication and HIV-1 strains resistant to a nonnucleoside reverse transcriptase inhibitor (NNRTI) and other antiretroviral agents."[39]

38. Note that during the relevant period (2006-2014), the approved indication for Intelence never included treatment-naïve HIV patients.

39. The initial 2006 FDA-approved labeling for Prezista limits "indications and usage" to the following:

"PREZISTA, co-administered with 100 mg ritonavir (PREZISTA/rtv), and with other antiretroviral agents, is indicated for the treatment of human immunodeficiency virus (HIV) infection in antiretroviral treatment-experienced adult patients, such as those with HIV-1 strains resistant to more than one protease inhibitor."[40]

40. In December 2008, the FDA-approved labeling for Prezista changed to remove the limitation to treatment-experienced patients only and expanded use for patients 6 years of age and older:

"*PREZISTA is a human immunodeficiency virus (HIV-1) protease inhibitor indicated for the treatment of HIV infection in adult patients. PREZISTA is also indicated for the treatment of HIV infection in pediatric patients 6 years of age and older. PREZISTA must be co-administered with ritonavir (PREZISTA/rtv) and with other antiretroviral agents."*[41]

Consistent with this change in the label, I understand that Plaintiffs have only challenged the prescriptions of Prezista to treatment-naïve patients during the period from 2006-2008.

41. *AHFS Drug Information* similarly states that the indication was initially limited to treatment-experienced adults:

"*Darunavir with low-dose ritonavir (ritonavir-boosted darunavir) is used in conjunction with other antiretroviral agents for the treatment of human immunodeficiency virus (HIV) infection in treatment-experienced*

[39] American Society of Health-System Pharmacists. Etravirine. In: *AHFS Drug Information 2010*. Bethesda, MD: American Society of Health-System Pharmacists

[40] Prescribing information for Prezista- 2006 https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/021976lbl.pdf

[41] Prescribing information for Prezista- 2008 https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021976s009lbl.pdf

(previously treated) adults, including those infected with HIV-1 strains resistant to multiple HIV protease inhibitors (PIs).”[42]

42. Prescriptions for Prezista or Intelence for treatment-naïve patients during any time that the label stated that the medications were to be used for only treatment-experienced patients are clear examples of prescriptions that are not medically indicated and are not reimbursable by Medicare Part D. Additionally, any prescriptions that do not meet other conditions specified in the approved indications (e.g., patient age requirements, requirements for concurrent combination therapy, etc.) are not reimbursable by Medicare Part D.

43. The definition of “off-label usage” that is commonly understood in the pharmacy profession is described in a *Health Affairs* article: “A drug is used off label any time it is administered in a way that is not been approved by FDA. This includes prescribing a drug for a different disease or symptom, in a population that has not been included in the label or with a different dosage level or formulation.”[43]

44. CMS confirms the “off-label” definition: “The use of pharmaceuticals for unapproved symptoms or conditions, in unapproved patient groups, or in unapproved dosages is referred to as ‘off-label.’”[44]

45. Edgar points out that the *Medicare Prescription Drug Benefit Manual* states the dose prescribed is not part of the indication for a drug;[45] however, she fails to address some significant points. First, the approved dosage and administration instructions are part of the FDA-approved label, and FDA does not seem to distinguish dosing from indication in a way that suggests that dosing is less important, at least not in an across-the-board manner. Indeed, FDA has acknowledged that judgment calls are made about where to include certain information, such as drug dosage, in a drug label, as demonstrated in the following FDA advice:

“IV. DISTRIBUTING INFORMATION AMONG SECTIONS

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[42] American Society of Health-System Pharmacists. Darunavir. In: *AHFS Drug Information 2007.* Bethesda, MD: American Society of Health-System Pharmacists

[43] Richardson, E., “Off-Label Drug Promotion,” Health Affairs, June 30, 2016. Found at: https://www healthaffairs.org/do/10.1377/hpb20160630.920075/full/ (Accessed January 10, 2020)

[44] CMS, “Off-Label Pharmaceutical Marketing: How to Recognize and Report It.” Found at: https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/off-label-marketing-factsheet.pdf (Accessed January 10, 2020.) While this document refers to Medicaid, CMS is also responsible for financing and administering the Medicare program. The cases cited by CMS in this article refer to fraudulent claims in both Medicaid and Medicare.

[45] Edgar Report, paragraph 18.

> *When creating labeling in PLR format or converting labeling in the old format to the PLR format, applicants face many decisions about how to distribute information among labeling sections. Often sections or subsections can be moved with little or no modification (see Appendix C). In some cases, it will be more appropriate to move certain information from a labeling section in the old format to a different labeling section in the PLR format or to consolidate similar issues in one place. In other cases, it will be appropriate to divide portions of information in a single labeling section among two or more sections. The following general principles and examples are offered to help applicants make decisions about how to organize information. These considerations apply whether revising labeling from the old format or creating new labeling."*[46]

46. Additionally, there are instances of drug labels where what might have been included as dosing or administration information was, in fact, incorporated into the Indications and Usage section of the FDA label. The following are two examples:

(1) The indications for Zantac (ranitidine) provide the dose for treatment of gastroesophageal reflux disease (GERD) as 150 mg BID and the dose for treatment of endoscopically diagnosed erosive esophagitis as 150 mg. QID.

(2) Epzicom is a nucleoside reverse transcriptase inhibitors (NRTI), a type of ARV medication. The label indications warns that hypersensitivity reactions for a similar NRTI medication are more likely when taken 600 mg QD versus 300 mg BID. The "dosage and administration" section of the approved labeling for Epzicom refers back to dosage information in the "indications and usage" section of the label.

Clearly, label indications and dosage are closely entwined and not mutually exclusive issues. The fact is that dosages can be, and are, included as part of indications.

47. Moreover, in the case of ARV drugs, it is not clear that "QD" versus "BID" is considered simply a dosing issue, particularly for this kind of therapeutic treatment where that issue is so critically important for the medication to effectively treat the patient's condition. As Dr. Glatt explained, "Dosing an antiretroviral medication once daily when it is required to be taken twice daily poses serious concerns of patient harm because the drug may not be effective for the full 24 hours between doses. This may leave the patient 'uncovered' part of the day and allow the existing virus to potentially mutate and become resistant to drug treatment."[47]

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[46] Food and Drug Administration, *Guidance for Industry*, *Labeling for Human Prescription Drug and Biological Products – Implementing the PLR Content and Format Requirements*, (Feb. 2013), p. 4.. Found at: https://www fda.gov/media/71836/download

[47] Glatt Report, paragraph 83

48. Notably, in internal documents as well as press releases, Janssen frequently used the terminology interchangeably or loosely.

(1) For instance, an internal Janssen PowerPoint called "HIV Franchise Objection Handling Research" dated March 14, 2011 has a slide that discusses how a sales rep should respond to a physician stating "If I could dose INTELENCE QD, it would make a difference."[48] The slide notes that "[m]ost [physicians] are inclined to wait to see if INTELENCE actually receives a QD indication before changing their behavior, especially after seeing the outcome of the Isentress QD studies" and states that "INTELENCE is indicated for use BID – just one 200mg pill, twice daily."

(2) Similarly, an internal Janssen presentation titled "INTELENCE QD Trial Analysis & Commercial Valuation," dated March 16, 2011 states "Do we want a QD indication in package insert? YES, ideally. For all indicated population or a segment (EE) of indicated population".[49]

(3) In a news release dated October 22, 2008, Janssen stated that Prezista received "approval for an expanded indication for once-daily dosing."[50]

(4) In another news release dated February 4, 2009, the company says that the European Union's approval of once-daily Prezista "broadens the previous indication of darunavir for treatment-experienced HIV-1 patients."[51]

(5) An industry publication was titled "Once-daily darunavir (Prezista) approved for first-line use" [52]

49. The Relators allege that both Prezista and Intelence were marketed for off-label use and that this marketing was a substantial factor in causing the use of the products that was not

48 JANSSEN_PI_00625252 at 32

49 JANSSEN_PI_00143462 at 10

[50] News Release "U.S. Food and Drug Administration (FDA) Approves Prezista Once-Daily as Part of Combination Therapy for Treatment-Naive Adults with HIV-1" (October 22, 2008). https://johnsonandjohnson.gcs-web.com/news-releases/news-release-details/us-food-and-drug-administration-fda-approves-prezistar-once/

[51] News Release "Once-Daily Prezista (darunavir) for Treatment-Naïve Adults with HIV-1 Receives Approval in the European Union as Part of Combination Therapy" (February 3, 2009https://johnsonandjohnson.gcs-web.com/news-releases/news-release-details/once-daily-prezistar-darunavir-treatment-naive-adults-hiv-1

[52] Alcorn K, "Once-daily darunavir (Prezista) approved for first-line use in United States," Aidsmap.com News (October 22, 2008). http://www.aidsmap.com/news/oct-2008/once-daily-darunavir-prezista-approved-first-line-use-united-states

medically necessary or reasonable.[53]

50. Edgar also asserts that "Part D beneficiaries…may receive coverage for FDA-approved drugs that are prescribed for a 'medically accepted indication…' [but that] Part D does not require that a drug be 'reasonable and necessary' to be covered under the benefit."[54] I agree that a medically accepted indication is one requirement for Medicare Part D coverage.[55,56]

51. I disagree, however, with Edgar's conclusion that there is no requirement under Part D that drug use be medically reasonable and necessary. I note that this appears to be a legal conclusion, based on an interpretation of statutes and regulations. In that regard, I am aware that the court hearing this action has already ruled that Part D incorporates the requirement that a drug be medically reasonable and necessary.[57] That ruling appears to have been based, in part, on a decision by the Third Circuit Court of Appeals,[58] all of which is consistent with my view that this is a legal issue, and is also consistent with my view that such a requirement is, indeed, in place under Medicare Part D.

52. I am also aware that other courts have reached similar conclusions, such as *Diamond v. Secretary of Health & Human Services*:

> The relevant statutes create two requirements for medication coverage under part D. The first is a general one: Congress has prohibited payment under part D for 'any expense incurred for items or services [that] are not reasonable and necessary for the treatment of illness or injury or to improve the functioning of a malformed body member.' See 42 U.S.C. § 1395w–102(e)(3) (incorporating the reasonable and necessary requirement of 42 U.S.C. § 1395y(a), quoted). The second, discussed at length above, requires that the medication be prescribed for a 'medically accepted indication.' 42 U.S.C. § 1395w–102(e)(1). These two requirements are not alternative tests for coverage. Rather, a medication must satisfy both requirements—i.e., it must be both 'reasonable and necessary' and prescribed for a 'medically accepted indication'—in order to require

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[53] *Second Amended Complaint*, pp. 2-7

[54] Edgar Report, paragraph 9. This assertion about the lack of a medical necessity requirement under Part D is repeated in paragraph 19: "[CMS, under Part D,] does not review prescription drug claims on a claim-by-claim basis and does not consider whether a prescription is 'reasonable and necessary' to treat a particular illness when determining if it is a covered Part D drug."

[55] 42 C.F.R. § 423.100

[56] *Medicare Prescription Drug Benefit Manual*, ch. 6, § 10.6

[57] *United States ex rel. Penelow v. Johnson & Johnson*, 2017 WL 2367050 at *5 (D.N.J., May 31, 2017)

[58] *United States ex rel. Petratos v. Genentech, Inc.*, 855 F.3d 481, 487-89 (3d Cir. 2017)

coverage under Part D.[59]

53. Based on my experience and understanding of how CMS operates in the Part D realm, it is apparent that CMS does care that health services are medically necessary and reasonable. Various provisions from the *Medicare Prescription Drug Benefit Manual* support this conclusion, including, for example, the express provision that certain utilization management edits by a sponsor during the plan year do not require CMS submission or approval, including specific references to "safety edits to prevent dispensing of unsafe dosing of drugs," and "incorrect drug dosage or duration of drug therapy."[60] Even the section of the *Manual* addressing the requirement that all ARV drugs be on formulary explains that requirement out of concern that there is no detrimental interruption of therapy.[61] Further, as noted above, the quality assurance regulations require Part D plans to have systems in place to improve medication use by ferreting out "inappropriate or medically unnecessary care among enrollees."[62] Additionally, I am not aware of CMS ever stating that it does not matter for purposes of Part D whether a drug is medically necessary and reasonable.

54. Dr. Edgar states that CMS, under Part D, "does not review prescription drug claims on a claim-by-claim basis and does not consider whether a prescription is 'reasonable and necessary' to treat a particular illness when determining if it is a covered Part D drug."[63] She implies that this indicates CMS' indifference to whether prescriptions were for medically indicated uses or were medically necessary and reasonable.

55. As discussed previously, the data submitted to CMS on the PDE does not contain patient diagnoses, indications, directions for use and other data that would allow CMS to detect whether prescriptions are written off label or don't meet the reasonable and necessary standard. This should not be misconstrued to suggest that this undermines the established requirements for reimbursability.

56. Additionally, nothing that Edgar cites about overall federal policies supporting aggressive and comprehensive treatment of HIV/AIDS patients undermines the core requirement that drug usage must be medically necessary and reasonable in order to be reimbursable under Part D. To the contrary, it is my understanding that CMS is fundamentally concerned with the appropriateness of medical treatment and that concern is as applicable in the HIV/AIDS field as elsewhere. Notably, in the section of the *Medicare*

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[59] *Diamond v. Secretary of Health & Human Services* No. 1:13 CV 2481, 2015 WL 367010, at *6 (N.D. Ohio Jan. 27, 2015)

[60] *Medicare Prescription Drug Benefit Manual*, ch. 6, § 30.2.2.2

[61] *Medicare Prescription Drug Benefit Manual*, ch. 6, §30.2.5

[62] 42 C.F.R. 423.153

[63] Edgar Report, paragraph 19

Prescription Drug Benefit Manual addressing the requirement to include all drugs in the ARV class on Part D plan sponsors' formularies, it states that "CMS instituted this policy because it was necessary to ensure that Medicare beneficiaries reliant upon these drugs would not be substantially discouraged from enrolling in certain Part D plans, as well as to mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations."[64] As Dr. Glatt explains, interruption of therapy is particularly problematic for HIV/AIDS patients because of viral replication, which the improper use of ARVs on a once-daily basis fails to prevent.[65]

57. Federal policy to provide quality care and to reduce transmission of HIV/AIDS depends on using drugs so as to achieve maximum suppression, which not only protects the individual patient, but also reduces transmission of the disease to others.[66] In his report, Dr. Glatt points out that Janssen's promotion of off-label use of Prezista and Intelence for treatment naïve patients as well as promotion for off-label once-daily dosing of Intelence undermines the goals of quality care for patients and the population overall. He notes that this inappropriate treatment would have been expected to lead to instances of patients suffering harm by developing resistance to those ARVs prematurely and the transmission of the disease would increase.[67]

58. Dr. Glatt also concluded that "prescriptions for Prezista as a result of Janssen's false and misleading promotion about Prezista's lipid profile were not appropriate treatment of patients who had concerning levels of lipids, triglycerides and/or cholesterol."[68] He goes on to describe how some Prezista prescriptions do not meet the standards of good medical practice.[69] Off-label marketing of unfounded "lipid neutral" claims for Prezista undermines the quality care goal because unnecessary use of Prezista would exacerbate already existing lipid/cholesterol problems.

59. It is my opinion that CMS does maintain a "medically necessary and reasonable" requirement for services under Part D and, based on Dr. Glatt's opinion, that prescriptions relying on Janssen's false and misleading marketing do not meet this standard and should not be covered.

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[64] *Medicare Prescription Drug Benefit Manual*, ch. 6 § 30.2.5

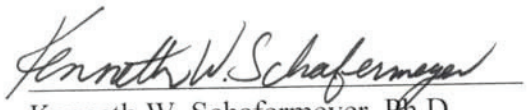
[65] Glatt Report, paragraphs 38 and 80

[66] Edgar cites a CMS document in paragraph 25 that supports this point.

[67] Glatt Report, paragraphs 108 and 142

[68] Glatt Report, paragraph 177

[69] Glatt Report, paragraphs 178-182



Kenneth W. Schafermeyer, Ph.D.
January 31, 2020

Exhibit A

Curriculum Vitae
of
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ACADEMIC INTERESTS

- **Teaching:** Economics, Pharmacy Management, Financial Management and Managed Health Care.
- **Research and Consultation:** Health economics, health systems management, financial analysis of pharmacy operations, Medicaid and managed care prescription programs, public policy issues related to medication usage and optimizing use of pharmacy technical support.

EDUCATION

1990	Doctor of Philosophy in Pharmacy Administration, School of Pharmacy and Pharmacal Sciences, Purdue University, West Lafayette, Indiana.
1983-1987	School of Business, Washburn University, Topeka, Kansas (36 credit hours of business, economics and marketing).
1979	Master of Science in Pharmacy Administration, School of Pharmacy, University of Tennessee, Memphis, Tennessee.
1976	Bachelor of Science in Pharmacy, St. Louis College of Pharmacy, St. Louis, Missouri.

LICENSURE AND CERTIFICATION

- Currently licensed as a pharmacist by examination in Missouri (1976) and formerly licensed by reciprocity in Tennessee (1978) and Virginia (1979).
- Designated as a "Certified Association Executive" by the American Society of Association Executives (1981).

EMPLOYMENT HISTORY

2012 -	Professor of Pharmacy Administration and Director, Office of International Programs, St. Louis College of Pharmacy
2007-2012	Professor of Pharmacy Administration and Director, Liberal Arts and Administrative Sciences Division, St. Louis College of Pharmacy.

2001-2007	Professor of Pharmacy Administration and Director of Graduate Studies, St. Louis College of Pharmacy.
2002-2003	Senior Fellow, Institute for the Advancement of Community Pharmacy (sabbatical assignment July 1, 2002 to June 30, 2003).
1996-2001	Associate Professor of Pharmacy Administration and Director of Graduate Studies, St. Louis College of Pharmacy.
1995-1996	Associate Professor of Pharmacy Administration, St. Louis College of Pharmacy.
1990-1995	Assistant Professor of Pharmacy Administration, St. Louis College of Pharmacy.
1988-1990	Graduate Teaching Assistant and Research Assistant, Purdue University School of Pharmacy and Pharmacal Sciences.
1982-1987	Executive Director, Kansas Pharmacists Association; Executive Director, Kansas Pharmacy Foundation; Executive Vice President, Kansas Society of Hospital Pharmacists; and Executive Director, Kansas Pharmacy Service Corporation.
1979-1982	Executive Director, Virginia Pharmaceutical Association; and Executive Director, Virginia Pharmaceutical Association Research and Education Foundation.
1978-1979	Assistant Executive Director, American College of Apothecaries; Graduate Teaching Assistant, University of Tennessee School of Pharmacy; Staff Pharmacist, White Way Drug, Memphis, Tennessee; and Relief Pharmacist, various pharmacies in Memphis, Tennessee.
1976-1978	Director of Professional Relations, Missouri Foundation for Pharmaceutical Care; Staff Pharmacist, Kirkwood Drug, Kirkwood, Missouri; and Relief Pharmacist, various pharmacies in the St. Louis area.
1973-1976	Pharmacy Intern, Glasgow Pharmacy, St. Louis, Missouri.

ASSOCIATION MEMBERSHIPS

Academy of Managed Care Pharmacy
American Association of Colleges of Pharmacy
American College of Apothecaries (1978-87)
American Pharmacists' Association
American Society of Association Executives (1979-88)
American Society of Hospital Pharmacists (1988-93)
Indiana Pharmacists' Association (1988-1990)
International Pharmacy Federation
International Society for Pharmacoeconomics and Outcomes Research (1995-2001)
Kansas Pharmacists' Association (Honorary Life Member)
Kansas Society of Association Executives (1982-88)
Lambda Chi Alpha Fraternity
Missouri Pharmacy Association

NAFSA: Association of International Educators
National Community Pharmacists' Association
National Council of State Pharmaceutical Association Executives (1979-88)
National Organization for Competency Assessment (2006-09)
Phi Lambda Sigma Pharmacy Leadership Society
Rho Chi Pharmacy Honor Society
St. Louis Pharmacists' Association (1991-2008)
St. Louis College of Pharmacy Mortar and Pestle Club
Virginia Pharmaceutical Association (1979-82)
Virginia Society of Association Executives (1979-82)

RESEARCH AND SCHOLARLY ACTIVITIES

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Yates WN, Kuhn JJ, Thatcher K, and Schafermeyer KW (eds.). *The Return Goods Policy Manual, Fourth Edition* (Topeka, KS: Kansas Pharmacists Association, 1987).

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Schafermeyer KW “Integration of Managed Care in the Pharmacy Curriculum.” NABP/AACP Region VI Annual Meeting, Lawrence, KS, October 5, 2001.

Schafermeyer KW, “How Do Countries Differ Regarding Drug Policies?” International Students’ Organization, St. Louis College of Pharmacy, September 18, 2001.

Schafermeyer KW, “Self Assessment of Learning in a Graduate Program in Managed Care Pharmacy.” International Pharmaceutical Federation Annual Congress, Singapore, September 2, 2001.

Schafermeyer KW, Hurd PH and Rickert DR, “The Portfolio’s Role in Changing Graduate Students’ Perceived Self Efficacy.” Poster, American Association of Colleges of Pharmacy Annual Meeting, Toronto, Canada, July 9, 2001.

Schafermeyer KW, “How to Enhance Your Career as a Pharmacy Technician.” Missouri Pharmacists Association Annual Meeting, Osage Beach, MO, June 16, 2001.

Schafermeyer KW, “Development of a Formulary System.” Kanartaka State Pharmacy Council, Bangalore, India, May 17, 2001.

Schafermeyer KW, “Evolution of Pharmacy Practice and Education in the United States: From Compounding to Pharmaceutical Care.” Al-Ameen College of Pharmacy, Bangalore, India, May 21, 2001.

Schafermeyer KW, “Opportunities in Pharmacy Ownership.” National Community Pharmacists Association Chapter at the St. Louis College of Pharmacy, September 7, 2000.

Schafermeyer KW, “How to Effectively Train Pharmacy Technicians.” Missouri Pharmacy Association Annual Meeting, Osage Beach, MO, June 10, 2000.

Schafermeyer KW, “Cracking the Code: Understanding Third-Party Plans.” National Community Pharmacists Association Annual Meeting, Las Vegas, NV, October 24, 1999.

Schafermeyer KW, “Pharmacy Law and You: Laws That Affect Your Day.” National Community Pharmacists Association Annual Meeting, Technician Program, Las Vegas, NV, October 24, 1999.

Moderator for Giambrone A and Gordon DK, “Data Warehousing and Pharmacy: Integrating Information for Improved Decision Making.” Academy of Managed Care Pharmacists Annual Meeting, Atlanta, GA, October 9, 1999.

Schafermeyer KW, “How to Effectively Train Your Pharmacy Technicians.” Cardinal Health Retail Business Conference, Washington, DC, July 20, 1999.

Schafermeyer KW, “Managed Heath Care: A Primer for Pharmacy Technicians.” Cardinal Health Retail Business Conference, Washington, DC, July 19, 1999.

Rascati KL, Drugalis JR, Larson LN and Schafermeyer KW, “Pharmacoeconomic Education in Colleges of Pharmacy: A Panel Discussion.” American Association of Colleges of Pharmacy Annual Meeting, Boston, MA, July 7, 1999.

Moderator for Bertin RJ and Bond WE, “Credentialing: Documenting Pharmacists’ Knowledge and Skills.” Academy of Managed Care Pharmacy Annual Meeting, Minneapolis, MN, April 30, 1999.

Schafermeyer KW and Chereson RS, “Be Prepared: Pharmacy Technician Certification Exam Review.” National Community Pharmacists Association Annual Meeting, St. Louis, MO, October 17, 1998.

Schafermeyer KW, “Advancing Your Career as a Pharmacy Technician.” National Community Pharmacists Association Annual Meeting, St. Louis, MO, October 17, 1998.

Schafermeyer KW, “Ask the Experts: Round Table Discussion for Pharmacy Students.” Academy of Managed Care Pharmacy Educational Conference, Chicago, IL, October 9, 1998.

Schafermeyer KW, “Master of Science Courses in Managed Care Pharmacy.” Poster, American Association of Colleges of Pharmacy Annual Meeting, Snowmass, CO, July 21, 1998.

Schafermeyer KW, “Round Table Discussion for Pharmacy Students: Graduate Study in Managed Care Pharmacy.” Academy of Managed Care Pharmacy Educational Conference, Chicago, IL, October 8, 1998.

Moderator for Sorensen TD, “Expectations of a Managed Care Student Clerkship Rotation.” Academy of Managed Care Pharmacy Educational Conference, Chicago, IL, October 8, 1998.

Schafermeyer KW, “Preparing Abstracts and Presentations.” Academy of Managed Care Pharmacy Annual Meeting, Philadelphia, PA, May 1, 1998.

Schafermeyer KW, “Training Your Pharmacy Technicians.” National Community Pharmacists Association Rx Expo, Pittsburgh, PA, May 8, 1998.

Schafermeyer KW, “Opportunities in Managed Care,” NCPA Career Round Tables, NCPA Annual Meeting, Denver, CO, October 26, 1997.

Wagner MA and Schafermeyer KW, “Introduction of the NACDS Technician Competency Exam.” National Association of Chain Drug Stores Pharmacy Conference, Boston, MA, August 25, 1997.

Schafermeyer KW, “Role of the Technician in Patient-Focused Care.” Wisconsin Pharmacists Association Annual Meeting, Madison, WI, August 16, 1997.

Schafermeyer KW, “Technician Training.” Wisconsin Pharmacists Association Annual Meeting, Madison, WI, August 16, 1997.

Hobson EH, Holiday-Goodman MG, Schafermeyer KW and Smith RE, "Taking the Plunge: Introducing Writing in Pharmacy Courses." American Association of Colleges of Pharmacy Annual Meeting, Indianapolis, IN, July 15, 1997.

Schafermeyer KW and Hobson EH, "Business Plans: A Tool to Teach Entrepreneurial and Communication Skills." Poster, American Association of Colleges of Pharmacy Annual Meeting, Indianapolis, IN, July 15, 1997.

Schafermeyer KW, Hurd PD and Motheral BR, "Managed Care Pharmacy: M.S. Degree and Certificate Program." Poster, American Association of Colleges of Pharmacy Annual Meeting, Indianapolis, IN, July 13, 1997.

Dolinsky D, Brushwood D, Desselle S, Mount J, Schafermeyer K and Stratton T, "Social and Administrative Sciences Instructional Modules for the Delivery of Pharmaceutical Care-1997." Poster, American Association of Colleges of Pharmacy Annual Meeting, Indianapolis, IN, July 15, 1997.

Schafermeyer KW, "Writing to Learn Workshop." North Dakota State University Faculty Retreat for Colleges of Pharmacy and Nursing, Fargo, ND January 6, 1997.

Schafermeyer KW and West DS, "Independent Pharmacy Career Roundtable." NARD Annual Meeting, New Orleans, LA, October 13, 1996.

Motheral BR and Schafermeyer KW, "Using Claims Databases for Pharmacoeconomic Analysis and Outcomes Management." Academy of Managed Care Seminar titled "Linkages for Quality: Information Management for Managed Care Pharmacy," Chicago, IL, September 16, 1996.

Schafermeyer KW, "How to Train and Manage Pharmacy Technicians." Georgia Pharmacists' Association Annual Meeting, Savannah, GA, June 18, 1996.

Schafermeyer KW and Motheral B, "Pharmacoeconomics: Basic Principals." SmithKline Beecham Pharmaceuticals Regional Managers Meeting, Memphis, TN, December 4, 1995.

Schafermeyer KW, "Training Your Pharmacy Technician: A Tool for Building a Better Team." NARD Annual Meeting, Las Vegas, NV October 10, 1995.

Chereson RS, Bilger R, Miller B, Schafermeyer KW, "Pharmacy Practitioners' Perceptions of the Pharmaceutics Curriculum." Poster, Annual Meeting of the American Association of Colleges of Pharmacy, Philadelphia, PA, July 1995.

Schafermeyer KW, "The Pharmacy Technician's Role in Enhanced Patient Care." NARD Rx Expo, Dallas, TX, May 6, 1995.

Schafermeyer KW, "Patient Outcomes Measurement and Pharmacoeconomics: Basic Principals." Sixth Annual Charles C. Rabe Symposium, St. Louis, MO, April 25, 1995.

Schafermeyer KW, "Reforming Mental Health Care Prescription Coverage." First Annual Meeting of the Psychopharmacy Pharmacists, St. Louis, MO, November 5, 1994.

Schafermeyer KW, "Health Care Reform: The State Challenge." Illinois Pharmacists Association Annual Meeting, St. Louis, MO, September 30, 1994.

Schafermeyer KW, "Pharmacy Education Reform: Consequence of Health Care Reform." Faculty Retreat of the St. Louis College of Pharmacy, Grafton, IL, August 17, 1994.

Schafermeyer KW, “Using Spreadsheets for Case Studies in Pharmacy Management.” American Association of Colleges of Pharmacy Annual Meeting, Section of Social and Administrative Sciences, session titled “Round Tables on Educational Strategies and Innovations.” Albuquerque, NM, July 17, 1994.

Hobson EH and Schafermeyer KW, “Writing and Critical Thinking: Writing to Learn.” American Association of Colleges of Pharmacy Annual Meeting, Special Session titled “Classroom Strategies for Developing Critical Thinking.” Albuquerque, NM, July 19, 1994.

Schafermeyer KW, Hobson E, Goodwin SA, and Tadrus CS, “Writing-to-Learn in Large Classes: Student and Instructor Benefits.” American Association of Colleges of Pharmacy Annual Meeting, Albuquerque, NM, July 19, 1994. Also presented at the Second International Writing Centers Conference, St. Louis, MO, September 28, 1995.

Schafermeyer KW, “Health Care Reform: Implications for Pharmacy.” Connecticut Pharmacists Association Annual Meeting, Southbury, CT, June 18, 1994.

Schafermeyer KW, “Seeds of Change: State Initiatives to Health Care Reform.” Continuing education program for the St. Louis College of Pharmacy Alumni Association, St. Louis, June 5, 1994.

Schafermeyer KW, “Marketing of Pharmaceuticals to Physicians.” Jewish Hospital Therapeutic Conference, St. Louis, MO, June 1, 1994.

Cataldo R and Schafermeyer KW, “Advanced Techniques for Managed Care Pharmacists.” Academy of Managed Care Pharmacy post-meeting seminar, Boston, MA, May 10-11, 1994.

Schafermeyer KW, “Value of Prescription Drug Therapy: Costs vs. Quality.” Meeting of Nurses’ Advanced Practice-Missouri, St. Louis, MO March 14, 1994.

Schafermeyer KW, “Health Care Reform: Implications for Pharmacy Education.” St. Louis College of Pharmacy Symposia, October 7, 1993.

Schafermeyer KW, “Health Care Reform: Changing the Face of Pharmacy.” St. Louis Pharmacists Association, November 16, 1993.

Schafermeyer KW, “Health Care Reform.” St. Louis College of Pharmacy Alumni Association, Columbia, MO, September 8, 1993

Schafermeyer KW, “A Study of the Changes in Medicaid Utilization and Expenditures Associated With an Expanded Drug Formulary.” Poster, Annual Meeting of the American Association of Colleges of Pharmacy, San Diego, CA, July 13, 1993.

Bot JA, and Schafermeyer KW, “Perceived Needs of Pharmacy Students and Recent Graduates for Pharmacy Management Proficiency.” Poster, American Association of Colleges of Pharmacy Annual Meeting, San Diego, CA, July 13, 1993. Also presented at the Fourth Annual Research/Scholarly Activity Poster Presentation Day, St. Louis College of Pharmacy, April 23, 1993. (Received "Best Poster Award".)

Schafermeyer KW, “How Pharmacists Can Help Protect Your Health.” St. Louis Rotary Club, June 3, 1993.

Schafermeyer KW, “Implications of OBRA '90 for Pharmacy Practice.” Academy of Students of Pharmacy, St. Louis, September 22, 1992.

Schafermeyer KW, “Perspectives on the PMA-Coordinated Industry Program for Pharmacy Faculty.” American Association of Colleges of Pharmacy Annual Meeting, Washington, DC, July 14, 1992.

Becker ES, Coley RM, McKinnon G, Grotpeter P, and Schafermeyer KW, “The Development of a Convocation Series Designed to Enhance Student Professionalism.” American Association of Colleges of Pharmacy Annual Meeting, Washington, DC, July 14, 1992.

Schafermeyer KW, “The U.S. Health Care System: Paradox and Alternatives.” Current Topics Discussion Group, Chesterfield, MO, May 17, 1992.

Moderator, Third Annual Charles C. Rabe Seminar, St. Louis, MO, April 23, 1992.

Bourikas C, Boyd KL, and Schafermeyer KW, “Factors Influencing Medication Information Requests by Patients.” Third Annual Research/Scholarly Activity Poster Presentation Day, St. Louis College of Pharmacy, St. Louis, April 22, 1992.

Schafermeyer KW, and Cataldo R, “An Analysis of the Cost of Dispensing Third-Party and Private-Pay Prescriptions in Rhode Island.” Poster, American Pharmaceutical Association Annual Meeting, Section of Economic, Social and Administrative Sciences, San Diego, CA, March 15, 1992.

Schafermeyer KW, “Graduate School Opportunities.” Rho Chi luncheon, St. Louis College of Pharmacy, December 6, 1991.

Schafermeyer KW, “Prescription Program Cost Containment: Strategies that Work.” Southern Illinois Coal Company Benefits Meeting, Mt. Vernon, IL, May 8, 1991.

Schafermeyer KW, Schondelmeyer SW, Thomas J, and Proctor KA, “Analysis of Chain Pharmacies' Costs of Dispensing a Third Party Prescription.” American Association of Colleges of Pharmacy Annual Meeting, Salt Lake City, UT, July 8, 1990. Also presented at the Annual Research/Scholarly Activity Poster Presentation Day, St. Louis College of Pharmacy, April 24, 1991.

Schafermeyer KW, Schondelmeyer SW, Thomas KA, and Proctor KA, “Comparison of Prescription Department Cost Allocation Methods.” American Pharmaceutical Association Annual Meeting, Section of Economic, Social and Administrative Sciences, New Orleans, LA, March 10, 1991.

Schafermeyer KW, “The Impact of Managed Health Care on Pharmacy Practice and Education.” District VI AACP/NABP Annual Meeting, St. Louis, MO, October 7, 1990. Also presented at the Meeting of the Board of Trustees of the St. Louis College of Pharmacy, October 16, 1990.

Schafermeyer KW, “The Usefulness of the FDA Orange Book as a Guide for Drug Product Selection Decisions.” American Society for Pharmacy Law Annual Meeting, Anaheim, CA, April 10, 1989.

Schafermeyer KW, "The Impact of the Medicare Catastrophic Health Care Act on Pharmacy Practice." Indiana Pharmacists Association Midyear Meeting, Indianapolis, IN, April 2, 1989.

Schafermeyer KW, "How to Produce Professional and Profitable Association Publications." National Council of State Pharmaceutical Association Executives Annual Meeting, Chicago, IL, March 27, 1987.

Schafermeyer KW, "Marketing of a Provider-Sponsored Prescription Drug Program." National Association of Retail Druggists' PSAO Conference, Kansas City, MO, May, 1986.

Schafermeyer KW and Gee MA, "Report on State Pharmacy Association-Sponsored Volume Purchasing Programs and Pharmacy Services Administrative Organizations." National Council of State Pharmaceutical Association Executives Annual Meeting, San Francisco, CA, March, 1986.

Schafermeyer KW, "The National and Local Scene on Pharmacy Preferred Provider Organizations and Buying Groups." Missouri Valley Drug Associates Meeting, Kansas City, MO, December, 1985.

Yates WN, Schafermeyer KW and Hovancsak C, "A Study of the Effectiveness of Drug Utilization Review in Improving the Quality of Patient Care." American Pharmaceutical Association Annual Meeting, San Antonio, TX, February 1985.

Schafermeyer KW, Huffman DE, Huffman DC Jr. and Roberts KB, "The Effect of Copayment on Prescription Size under a Prepaid Prescription Program." American Association of Colleges of Pharmacy Annual Meeting, Scottsdale AZ, June 29, 1981.

Schafermeyer KW and White BD, "Consumer Representation on State Boards of Pharmacy: A Survey and Suggestions." American Society for Pharmacy Law Annual Meeting, Anaheim, CA, April 24, 1979.

Schafermeyer KW and Huffman DC, "An Analysis of Select Practitioner Organizations' Positions on the Basic Degree Required for Licensure as a Pharmacist." Joint Commission of Pharmacy Practitioners, Washington, DC, July, 1978.

Grants

Lukas S, Teshome B, Berhane H, Schafermeyer KW, Gattas N, Stevens A, Peters GL, Yohannes B and Solomon G, "Optimizing Pharmacists' Impact to Improve Patient Care in Ethiopia." Proposal for STAR Grant sponsored by USAID and Consortium of Universities for Global Health, August 2019. ($15,000 – not funded)

Schafermeyer KW, Joshi M, Lukas S, Peters GL, Park T, Micek ST, Teshome B, Desai VH and Vaidya R, "Promotion of Antibiotic Stewardship in Goa, India." Proposal for STAR Grant sponsored by USAID and Consortium of Universities for Global Health, August 2019. ($15,000 – not funded)

Lukas SK and Schafermeyer KW, "Determining the Long-Term Impacts of Pharmacy student Participation in International Service and Learning Opportunities." Sponsored by the Faculty Research Incentive Fund Grant, St. Louis College of Pharmacy. ($2,555)

Schafermeyer KW and Lukas SK, "Proposal to Increase Pharmacy Student Involvement in Study Abroad Programs." Sponsored by the U.S. Department of State and administered by Partners of the Americas, Washington, DC, August 2016 ($36,334).

Schafermeyer KW and Griggs SK, "A Study of Missouri Pharmacies' Costs of Dispensing Prescriptions." Missouri Department of Social Services, December 2013. ($150,500 – subcontract through University of Missouri-Kansas City for $55,000)

Lee SY, Griggs SK and Schafermeyer KW, "The Assessment of Cultural Competency among Pharmacy Students. Funded by STLCOP Research Incentive Fund, October 2012 ($10,000). [Renewed in 2013 and 2014 for $5,000 and $6,000, respectively.]

Schafermeyer KW and Mallinson K, "Proposal for a Partnership to Support Mid-level Pharmacy Professionals in South Africa by Strengthening the Pharmacy Technician Program at Nelson Mandela Metropolitan University." Sponsored by the U.S. Department of Health and Human Services, Health Resources and Services Administration, administered by the American International Health Alliance, February 2013 ($80,000) [Renewed for FY 2014-15, $80,000 plus $22,499 subgrant; renewed for FY 2015-16, ~ $80,000 and for FY 2016-17 ~$80,000]

Schafermeyer KW, "Practice Analysis for Mid-Level Pharmacy Practitioners in South Africa." Research conducted for Nelson Mandela Metropolitan University School of Pharmacy, Port Elizabeth, South Africa. August 2013.

PROFESSIONAL SERVICE ACTIVITIES

Academic

Referee

- *AAPS PharmSci* (1 manuscript)
- *American Journal of Health-System Pharmacists* (7 manuscripts)
- *American Journal of Pharmaceutical Education* (15 manuscripts)
- *The Consultant Pharmacist* (1 manuscript)
- *Clinical Therapeutics* (5 manuscripts)
- *Drug Intelligence and Clinical Pharmacy* (1 manuscript)
- *Journal of the American Pharmaceutical Association* (8 manuscripts)
- *Journal of Managed Care Pharmacy* (21 manuscripts)
- *Journal of Managed Pharmaceutical Care* (1 manuscript)
- *Journal of Pharmaceutical Marketing and Management* (7 manuscripts)
- *Journal of Pharmacy Teaching* (1 manuscript)
- *Journal of Research in Pharmaceutical Economics* (1 manuscript)
- *Pharmacy Education* (the Journal of the International Pharmacy Federation) (5 manuscripts)
- *Research in Social and Administrative Pharmacy* (6 manuscripts)
- Reviewer, "A Manual of Experiential Learning in a Managed Care Pharmacy," Academy of Managed Care Pharmacy, 2000.
- Reviewer, "Accreditation Standards and Learning Objectives for Residency Training in Managed Care Pharmacy," Academy of Managed Care Pharmacy and the American Society of Health-Systems Pharmacy.
- Reviewer, teaching module on Quality Assurance for the *Managed Care & Pharmacy Teaching Tool Project* sponsored by Hoechst Marion-Roussel.
- Member, Editorial Advisory Board, American Association of Pharmaceutical Scientists.

- Abstract reviewer for the Annual Meeting of the American Pharmaceutical Association, Section of Economic, Social and Administrative Sciences, 1994.
- GAPS Review Panel, American Association of Colleges of Pharmacy, 1992.
- Outside Reviewer for West Virginia University Senate Grant for Research or Scholarship, 1999.
- Outside Reviewer for Promotion and Tenure Committees: Drake University, 1999, 2005 and 2010, Virginia Commonwealth University, 2001, Duquesne University, 2001 and 2005, University of Texas, 2006, University of Oklahoma, 2010, University of Arizona, 2013, and Rhodes University, 2016.
- Reviewer, Knowlton C and Penna R, *Pharmaceutical Care, Second Edition* (Washington DC: American Pharmaceutical Association).

Medical College of Virginia School of Pharmacy:
- Appointed as Practitioner/Teacher, 1979-1981.
- Appointed as Clinical Instructor in Pharmacy, 1981-1982.

University of Kansas School of Pharmacy:
- Member, Dean's Advisory Council, 1983-1987.
- Instructor for seven graduate students enrolled in the University of Kansas' Master of Science program in Hospital Pharmacy, 1983-1986.

St. Louis College of Pharmacy:
- Faculty Senate, 2015-2018.
- Faculty Promotion and Tenure Committee, 2015-2018.
- Department Promotion and Tenure Committee, 2018-19.
- International Travel Oversight Committee (chair) 2015-Present .
- Strategic Planning Update Committee, 2016.
- Office of International Programs Strategic Planning Committee (co-chair), 2016-17.
- Academic Planning Committee, 2000.
- Ad hoc Committee on Academic Progression, 1999, 2001-02.
- Ad hoc Committee to Develop a Consulting/Service Organization, 1990.
- Ad hoc Committee to Develop Criteria for the Student Enrichment Award, 1998.
- Ad hoc Committee on Intercultural Issues, 2001-02
- Ad hoc Committee on Mathematics Proficiency (chairman), 2004.
- Administrative Review Committee for Dean of Students, 1996.
- Administrative Review for Vice President of Academic Affairs, 2000.
- Admissions Committee 1993-2000 (Chairman 1993-1995).
- Advisory Committee for B.S. in Pharmaceutical Sciences, 2001.
- Assessment Committee, 1995-1998.
- Assessment Council for Biostatistics Course, 1996.
- Clerkship Review Task Force, 1997.
- Committee on Continuing Education, 1994-1996.
- Committee to Enhance Professionalization, 1991-1992.
- Committee on Research, 1992.
- Curriculum Committee, 1996-2000, 2007-2012 (Chairman 1998-1999).
- Course Review Team for Externships and Clerkships (Chairman) 1997-1998.
- NABPLEX Subcommittee, 1997-1998.
- Guidelines for Elective Designations Subcommittee, 1999.
- Subcommittee on Student Retention Policies, 1994.
- Subcommittee on Patient Outcomes Management/Pharmacoeconomics, 1994-1995.
- Subcommittee on Policies and Procedures

- Practice Management, Population Health and Information Master Domains, (chair) 2010-11.
- Subcommittees on professional program, co-curricular program and elective tracks (2011-12).
- Critical Thinking Steering Committee, Fourth Year Team (Chairman) 1992.
- Dean's Selection Advisory Committee, 1995.
- Executive Committee, 2004 – 2012.
- Faculty Advisor, Delta Sigma Theta Fraternity, 1991-2002.
- Faculty Advisor, National Community Pharmacists Association (formerly NARD) Chapter, 1992-present.
- Faculty Advisor, Lambda Chi Alpha Fraternity, 2006-present.
- Faculty Affairs Committee, 1999-2003; chairman 2001-02.
- Faculty Governance Committee, 2004-2008, 2014-15.
- Faculty Research Incentive Fund, reviewer, 1997.
- FIPSE Grant Advisory Team (Title: "St. Louis College of Pharmacy Peer Education Program"), 1994-1996.
- FIPSE Grant Faculty Member (Title: "A Multi-Institutional Assessment Center Model to Facilitate Expansion of Ability-Based Education in Schools of Pharmacy"), 1993-1996.
- Graduate Studies Committee, 1990-present (Chairman 1996-present).
- Insurance Advisory Committee, 1992.
- Master Plan Technology Subcommittee, 2000.
- Peer Review Team (for various faculty members) 1994-1995.
- Pharmaceutical Care Laboratory Ad Hoc Planning Committee, 1997.
- Pharmacy Technician Training Advisory Committee, (Chairman) 1998-1999.
- "President's Cabinet" (Capital Giving Campaign), 1993.
- Promotion and Tenure Committee (chairman) 2004-2007, department chair, (2014-15), member 2015-present.
- Search Committee for StLCOP President, 1993-1994.
- Search Committee for a part-time economics professor, (Chairman) 1992.
- Self Study Steering Committee, 2001-02.
- Sociology Course Review, 1992.
- Spirit of Inquiry Ad Hoc Committee, 1990.
- Division Committee to Stimulate Student/Faculty Research and Scholarly Activity, 1991-92.
- Strategic Planning Committee's Enrollment Management Task Force, 1996.
- Strategic Planning Committee, Subcommittee for the External Environment (Chairman) 1992-1993.
- Strategic Planning Writing Committee, 2004
- Strategic Planning Subcommittee on Fundraising, 2005.
- Student Faculty Liaison Committee, 1990-1992.
- Student Status and Advancement Committee, 1991.
- Technology Committee, 2004-2007.
- International Travel Oversight Committee, 2014-15 (Chaiman)

St. Louis Community College
- Member, Pharmacy Technician Program Advisory Committee

Washington University in St. Louis, School of Medicine
- Member, Advisory Board for Global Health Scholars in Medicine

Associations

Academy of Managed Care Pharmacy:

- Contributing Editor for *Journal of Managed Care Pharmacy*, 1995-1998.
- Member, Editorial Advisory Board, 1995-1998.
- Member, Schools of Pharmacy Relations Committee, 1997-1998.
- Member, Special Projects Committee, 1998-2000 (Chairman, 1999-2000).
- Member, Educational Affairs Committee, 2001-2004 (Chairman 2003-2004).
- Member, Nominating Committee, 2004.
- Member, Fellow Selection Committee, 2004.
- Diplomat, St. Louis College of Pharmacy.

American Association of Colleges of Pharmacy:
- Chair, Social and Administrative Sciences Section, 2005-06
- Chair-Elect, Social and Administrative Sciences Section, 2004-05
- Graduate Research Liaison for the St. Louis College of Pharmacy, 1999-2001.
- Member, Ad Hoc Committee on Mentoring, Section of Teachers of Pharmacy Administration, 2000-2001.
- Member, Curriculum Development Committee, Section of Teachers of Pharmacy Administration, 1993-1996.
- Member, Health Organization and Government Affairs Committee, 1997-1998.
- Alternate Delegate, Council of Faculties, 1996, 1999.
- Member, Web Resources Committee, 1999-2000

American College of Apothecaries:
- Member, Third Party Committee, 1979-1987.

American Pharmaceutical Association
- Books and Electronic Products Editorial Advisory Board, 2003-06.

American Society of Association Executives:
- Chairman, Certified Association Executives' Exam Study Committee for Kansas, 1983.

Indiana Pharmacists Association:
- Member, Association Affairs Committee, 1989.
- Representative to Indiana Department of Public Welfare's Medicaid Pharmacy Reimbursement Task Force, 1989.

Iowa and Wisconsin Pharmacists Associations:
- Member, Pharmacy Technician Certification Review Series Advisory Committee

Kansas Society of Association Executives:
- Member, Board of Directors, 1987.
- Member, Annual Meeting Committee, 1986.
- Chairman, Strategic Planning Committee, 1985.

Missouri Pharmacy Association:
- Member, Nominating Committee, 2016-17.
- Member, Convention Planning Committee, 2004-2006, 2010-11.
- Chairman, Bylaws Committee, 1994-98, member 1992-1994.
- Member of MPA Council (Board of Directors), 1975-1976.
- Member of MPA Education Committee, 2007-2009, 2012.
- Reviewer, Student Business Plan Competition, 2014.
- Member, Development Workgroup for Missouri Care Network

National Community Pharmacists Association (formerly National Association of Retail Druggists):
- Member, Consumer Affairs and Public Relations Committee, 1987.
- Member, Third Party Steering Committee, 1986.
- Member, Third Party Committee, 1985.
- Faculty Advisor, 1992-present.

National Council of State Pharmaceutical Association Executives:
- Chairman, Program Committee, 1987.
- Member, Board of Directors, 1986 and 1987.
- Member, Program Committee, 1986.
- Member, Third Party Task Force, 1985 and 1986.

St. Louis College of Pharmacy Alumni Association:
- Member, Board of Directors 2009 - 2017
- Member, Budget and Financial Development Committee, 1991-1994, 2004-05, 2009-10.
- Member, Bylaws Revision Committee, 1992.
- Member, Fund for Excellence Committee, 1993-1994.
- Member, Mortar and Pestle Society Advisory Committee, 1998.
- Member, Student Affairs Committee, 1994-2000.
- Co-chairman, Community Service Committee
- Class Representative for Class of 1976 Reunion.
- Member, Nominations Committee, 2000-2002, 2015-16.
- Member, Governance Committee, 2013-2017.
- Member, Community Affairs Committee, 2012-2015.

St. Louis Pharmacists' Association
- Chairman of the Board, 2004
- President, 2003
- Secretary, 2001-02.
- Member, Board of Directors, 1996-2000.
- Co-chairman, Charles C. Rabe Scholarship Committee, 1997.

State Pharmaceutical Editorial Association:
- Vice-President, 1982.

Student American Pharmaceutical Association:
- Chapter President, St. Louis College of Pharmacy, 1975-1976.
- Region VI Coordinator, 1975.

Virginia Society of Association Executives:
- Member, Strategic Planning Committee, 1982.

Consultation

- Xcenda/Genentech Advisory Board, "Cost Effectiveness of Breast Cancer Treatments," 2012-2013.

- Director of Education, Institute for the Certification of Pharmacy Technicians, 2005-2010.

- Board of Advisors, PharmAccount, Inc., 2004-2009.

- Consultant for Third Party Solutions, Inc. in Minnesota workers' compensation prescription reimbursement appeal.

- Senior Fellow for Institute for the Advancement of Community Pharmacy, “Optimizing Community Pharmacy Effectiveness,” 2001-02.
- National Association of Chain Drug Stores, 2000. (Scope of Consultation: update test bank for the Community Retail Pharmacy Technician Exam and revise the third edition of the *Community Retail Pharmacy Technician Training Manual*.)
- Academy of Managed Care Pharmacy. Served as featured expert for the “Ask Your Colleague” page on the AMCP web site. Topic: Provider Profiling. May 16-31, 2000.
- Academy of Managed Care Pharmacy, 1998. (Scope of consultation: development of a background paper on certification for managed care pharmacists).
- National Association of Chain Drug Stores, 1997-2000. (Scope of consultation: preparation and analysis of multiple versions of the Community Pharmacy Technician Examination).
- Iowa Pharmacists Association and Wisconsin Pharmacists Association, 1997-1998. (Scope of consultation: reviewed pharmacy technician training manual and videotape program.)
- University of Colorado College of Pharmacy, 1996. (Scope of Consultation: cost of dispensing study for Colorado Medicaid program.)
- National Association of Chain Drug Stores, 1996. (Scope of consultation: Analysis of chain pharmacy manpower needs.)
- SmithKline Beecham Pharmaceuticals, 1995. (Scope of consultation: Conference on pharmacoeconomics and outcomes management.)
- National Association of Chain Drug Stores, 1995. (Scope of consultation: Analysis of chain pharmacies' costs of dispensing.)
- Proctor and Gamble Pharmaceuticals, 1994-1995. (Scope of consultation: Managed care reimbursement for controlled-release products.)
- Calgon Vestal Laboratories, 1994. (Scope of consultation: Marketing to managed care organizations and application of pharmacoeconomic principals to marketing efforts.)
- National Association of Chain Drug Stores, 1994. (Scope of Consultation: External reviewer for "Community Retail Pharmacy Technician Training Manual.")
- Catholic Materials Management Alliance, 1994. (Scope of Consultation: Analysis of "Pharmacy Services Survey" for 125 Catholic hospitals in the U.S.)
- General American Life Insurance Company, 1994. (Scope of consultation: pricing of injectable drugs for Medicare Part B claims.)
- International Medication Systems, Ltd., 1994. (Scope of consultation: Pharmacoeconomic Analysis of Parenteral Drug Delivery Systems.)
- Express Scripts, Inc., 1991-1993. (Scope of consultation: prescription utilization analysis, formulary management and drug utilization review.)
- Missouri Department of Administration, Division of Purchasing, 1992. (Scope of consultation: member of evaluation team reviewing proposals to conduct a therapeutically oriented drug use review program for the Missouri Medicaid prescription program.) (RFP B300627)

- Southern Illinois Coal Company Benefits Committee, 1991. (Scope of consultation: cost containment of drug benefit program and improvement of utilization and patient compliance.)

- Missouri Department of Family Services, Division of Medical Services, Medicaid Prior Authorization Task Force, Chairman, 1991. (Scope of consultation: formulary recommendations for exclusion and prior authorization of drugs in the Missouri Medicaid program.)

- Illinois Pharmaceutical Association, 1991. (Scope of consultation: reviewed and commented on a draft of an Employee Pharmacist Manual.)

- Rhode Island Pharmaceutical Association, 1990-1991. (Scope of consultation: conducted a study of pharmacies' costs of dispensing third party prescriptions and provided individual pharmacy analyses on request.)

- Pharmacy Network of Indiana, 1989-1990. (Scope of consultation: prepared a response to a request for proposal from Blue Cross/Blue Shield of Indiana for the establishment, operation and management of a pharmacy preferred provider program.)

- Indiana Department of Public Welfare, Medicaid Pharmacy Reimbursement Task Force Member, 1989. (Scope of consultation: analysis of cost savings from formulary decisions and other cost containment measures; recommendation of cost containment strategies.)

- Georgia Pharmaceutical Association, 1987. (Scope of consultation: development of a nonprofit Research and Education Foundation.)

- Kansas Optometric Association, 1985. (Scope of consultation: evaluation of association structure, programs and activities according to guidelines recommended by the American Society of Association Executives.)

- Virginia General Contractors' Association, 1981. (Scope of consultation: evaluation of association structure, programs and activities according to guidelines recommended by the American Society of Association Executives.)

- Virginia Coalition for Prevention of Venereal Disease, Board of Directors, 1979-1981.

Testimony Given at Trial or Deposition (since 2015)

- *United States ex rel. Proctor v. Safeway Inc.,* 2018.
- *United States ex rel. Schutte v. SuperValu Inc., et al*., 2018.
- *HM Compounding Services, LLC et al. v. Express Scripts, Inc*., 2018.
- *Wisconsin v. Watson Pharmaceuticals, et al.,* 2016

TEACHING RESPONSIBILITIES
Undergraduate:
- Advanced Pharmacy Practice Experience (APPE) Rotations, 2010-present
- WE 3570 – Personal Financial Management for the Healthcare Professional; fall, 2005-07.
- PSEL 4100 / WE 3735 – International Service Learning 2011-12 (Costa Rica), 2012-13 (Guatemala), 2013 (Poland), 2013-14 (Guatemala), 2014 (Romania), 2015 (Macedonia), 2016 (Guatemala), 2017 (Guatemala and Portugal), 2018 (Guatemala and Romania).
- Special Projects – Leadership in International Service 2015-present
- SP 4720 – Special Projects: Pharmacy Business Planning, fall, 2005.

- PA 5120 – Health Systems Management: Economic Aspects, spring and fall 2005-present.
- UMKC Course – The Economics of Health and Medicine (Live Distance Learning), fall 2004.
- PA 4102 and PA 3002 - Pharmacy Management, spring 1991-2002, Fall 2000-03.
- WE 4770 - Introduction to Pharmacy Entrepreneurship, fall 1996-2000, 2012.
- SS 2111 and SS 2511 - Economics, fall 1990-1995, 2003, fall and spring 2004-2010.
- SS 2111 (Barnes College of Nursing) - Economics, spring 1992 and fall 1993.
- PA 2112 - Health Care Systems, spring 1991-1993.
- PA 5701 - Special Projects (Intro. to Community Pharmacy Ownership), fall 1991.
- ST 5700 - Selected Topics - Community Pharmacy Ownership, fall 1993-1994.
- Research Method Methods – Pharm. D., guest lectures, spring 1991.
- SS 1100 - Freshman Seminar, guest lectures, fall 1993.
- TH 5002 - Therapeutics IV, guest lecturer on managed care, spring 1997.
- Clinical Seminar Course, guest lecturer, spring 2006, 2007.
- Preceptor, Administrative Rotation, STLCOP Experiential Program, 2007.

Graduate:

- PA 6190 - Managed Care Pharmacy, Trimester II (Jan-Mar) 1998, 2000, 2002, 2004, 2006.
- PA 6180 - Managed Health Care, Trimester III (Apr-June) 1997, 1999, 2001, 2004, 2006, Trimester II, 2005.
- PA 6770 - Financial Management, Trimester I (Sep-Nov) 1996, 1998, 1999, 2001, 2003, 2005, 2007.
- PA 6802 - Pharmacy Marketing, Trimester II (Jan-Mar) 1991 and 1995, Trimester I (Sep-Nov) 1992.
- PA 6517 - General Research Methods (assisted), Trimester I (Sep-Nov) 1990, Trimester III (Apr-June) 1993 and 1994.
- PA 6722 - Health Care and Public Policy, Trimester I (Sep-Nov) 1991, 1993, 1995. Trimester II (Jan-Mar) 1997, 1999, 2001, 2003, 2005.
- PA 6101 - Management of Human Resources, Trimester II (Jan-Mar) 1992.
- PA 6160 - Pharmacy Policy and Planning, Trimester III (Apr-June) 1994 and 1995.

PUBLIC SERVICE

- Better Healthcare for Africa (supporting Medical Missions at St. Albert's Mission Hospital in Zimbabwe)
  - Member, Board of Directors (2010 – present)
- Walbridge Settlement Foundation (supporting a medical clinic in Kyekyewere, Ghana)
  - Secretary, Board of Directors (2008- 2016)
- Leukemia and Lymphoma Society
  - Member, Patient Services Committee, 2001-2006
  - Sponsor, Light the Night Walk, 2002-2009
  - Participant, First Connection Program 2001 – 2006 (Chairman, 2003-05)
- Habitat for Humanity – St. Louis, local volunteer, 2001 - present
- Habitat for Humanity International, Global Village Missions (2001 – present)
  - Bangalore, India 2001
  - Durban, South Africa 2002 (Crew Leader)
  - Asuncion, Paraguay 2003
  - Gangwon-do, South Korea 2003
  - Ulan Bator, Mongolia 2003
  - Nicoya, Costa Rica 2004 (Team Leader)
  - Belize City, Belize 2004
  - Cartago, Costa Rica 2005 (Team Leader)
  - Barahona, Dominican Republic 2005
  - Temuco, Chile, 2006
  - Kumasi, Ghana, 2007 (Team Leader)
  - Cochabamba, Bolivia 2008
  - Gabarone, Botswana 2009 (Co-leader)

- My Tho, Vietnam 2011 (Co-leader)
- Leogane, Haiti 2011
- La Cruz, Costa Rica, 2012 (Team Leader)
- Beius, Romania, 2012
- Jutiapa, Guatemala, 2013 (Team Leader)
- Katowice, Poland, 2013 (Team Leader)
- Tecpan, Guatemala, 2014 (Team Leader)
- Raduati, Romania, 2014 (Team Leader)
- Veles, Macedonia, 2015 (Team Leader)
- Cape Town, South Africa, 2015
- Retalhuleu, Guatemala, 2016 (Team Leader)
- San Lucas Toliman, Guatemala, 2017 (Team Leader)
- Braga, Portugal, 2017 (Team Leader)
- Quetzaltenagro, Guatemala, 2018 (Team Coordinator)
- Constanta, Romania, 2018 (Team Leader)
- El Progresso, Guatemala, 2019 (Team Coordinator)
- Gliwice, Poland, 2019 (Team Coordinator)

• Medical Missions
  - Brace for Impact 46 and Pittsburg Kids Foundation, CHIDA Hospital and Clinic, Cap Haitien, Haiti, August, 2018.
  - Pittsburg Kids Foundation, Health needs assessment, CHIDA Hospital and Clinic, Cap Haitien, Haiti, October, 2015.
  - Raleigh Fitkin Memorial Hospital, Manzini, Swaziland, 2012, 2013.
  - Friends in Village Development, Bangladesh, Sylhet, Bangladesh, 2014.
• American International Health Alliance (supporting capacity building efforts of Nelson Mandela Metropolitan University School of Pharmacy, Port Elizabeth, South Africa) 2013 - present.

HONORS AND AWARDS

• Distinguished Alumnus, STLCOP Alumni Association, November 10, 2017.
• Bowl of Hygeia Award (from the American Pharmacists Association, APhA Foundation, National Association of State Pharmacy Associations, and the Missouri Pharmacy Association) June 2013
• Outstanding Educator Award – Teacher of the Year, St. Louis College of Pharmacy, 2012.
• Emerson Excellence in Teaching Award, 2012.
• STLCOP Alumni Association Community Service Award, September, 2011
• STLCOP Faculty Member of the Year Award, Missouri Pharmacy Association, June, 2009
• Faculty Advisor of the Year, St. Louis College of Pharmacy, May, 2009.
• Fellow of the American Pharmacists Association, March, 2008.
• Student Enrichment Award, St. Louis College of Pharmacy, 2006.
• Fellow of the Academy of Managed Care Pharmacy, March, 2003.
• Senior Fellow, Institute for the Advancement of Community Pharmacy, July 1, 2002 to June 30, 2003.
• Missouri Pharmacy Association “Making a Difference Award,” June 15, 2002.
• Honorary Member, Phi Lambda Sigma Pharmacy Leadership Society, February, 2001.
• Outstanding Achievement Award, St. Louis College of Pharmacy Alumni Association, October, 2000.
• Life Membership, Mortar and Pestle Society, St. Louis College of Pharmacy, 1999.
• Faculty Award for Excellence in Pharmacy Administration, National Community Pharmacists Association Foundation, 1998.
• Faculty Mentor Award, NACDS Education Foundation Community Pharmacy Essay Contest, May 1998. (For mentoring student Paul M Husemann with his second-place essay “Paving the Way to Pharmaceutical Care: A Chain-Sponsored Education Program.”)
• Outstanding Educator of the Year, St. Louis College of Pharmacy, 1996.

- Emerson Electric Excellence in Teaching Award, November 17, 1996.
- NCPA Chapter of the Year Award, 1996 and 1997; Chapter of the Year Runner-Up, 1995, 1998, 1999 (Faculty Advisor).
- Missouri Pharmacy Association President's Award, June, 1995.
- New Investigator Grant, American Association of Colleges of Pharmacy, 1991.
- Jenkins/Knevel Award for Excellence in Research, 1990, Purdue University, finalist.
- Pfizer-AFPE Pharmacy Administration/Pharmaceutical Marketing Fellow, 1989/1990.
- First place, National Association of Boards of Pharmacy Foundation Scholarship Competition, January, 1989.
- Member, Rho Chi National Pharmaceutical Honor Society.
- Honorary Life Membership, Kansas Pharmacists Association, December, 1987. (Only the second person to have been awarded this honor.)
- First prize, Sandoz Tenth Annual Medical Journalism Competition, 1985.
- McKesson & Robbins Leadership Award, May, 1976.

Nov 2019

Exhibit B
Materials Relied Upon

Material From This Litigation

Expert Report of Babette Edgar, PharmD, MBA, FAMCP, Nov. 26, 2019

Expert Report of Aaron Glatt, M.D., Nov. 27, 2019

U.S. v. Johnson & Johnson, CV127758MASLHG, 2017 WL 2367050 (D.N.J. May 31, 2017)

Second Amended Complaint Pursuant to the Federal False Claims Act, 31 U.S.C. §§ 3729 et *seq.* and Pendent State False Claims Acts, *United States ex rel Penelow v. Johnson & Johnson*, No. 3:12-cv-07758-MAS-LHG, Dkt. 90 (D.N.J. June 30, 2017)

Defendant Janssen Products, LP's Answer and Affirmative Defenses to Relators' Second Amended Complaint, *United States ex rel Penelow v. Johnson & Johnson*, No. 3:12-cv-07758-MAS-LHG, Dkt. 92 (D.N.J. June 30, 2017)

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JANSSEN_PI_00625252

Statutes and Regulations

42 U.S.C.A. § 1395w-102 (2018)

42 U.S.C.A. § 1320c-5 (1996 & 2011)

42 U.S.C. § 1395w-115 (2008)

42 U.S.C. § 1395y (2018)

42 C.F.R. § 423

42 C.F.R. § 423.100

42 C.F.R. § 423.104(e)

42 C.F.R. § 423.120(a)

42 C.F.R. § 423.120(b)(2)(i)

42 C.F.R. § 423.153

42 C.F.R. § 423.153(c)

42 C.F.R. § 423.153(d)

Cases

Diamond v. Sec'y of Health & Human Servs., No. 1:13 CV 2481, 2015 WL 367010 (N.D. Ohio Jan. 27, 2015)

United States ex rel. Petratos v. Genentech Inc., 855 F.3d 481 (3d Cir. 2017)

Other Material

Alcorn K, *Once-daily darunavir (Prezista) approved for first-line use in United States* (October 22, 2008), Aidsmap.com News, available at http://www.aidsmap.com/news/oct-2008/once-daily-darunavir-prezista-approved-first-line-use-united-states (last visited Jan. 31, 2020)

American Society of Health-System Pharmacists, AHFS Drug Information (2007)

American Society of Health-System Pharmacists, AHFS Drug Information (2010)

American Society of Health-System Pharmacists, AHFS Drug Information (2014)

Boards of Trustees of the Federal Hospital Insurance and Federal Supplemental Medical Insurance Trust Funds, Annual Report (2017), available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2017.pdf (last visited Jan. 31, 2020)

CMS, *Brief Summaries of Medicare & Medicaid, Title XVIII and Title XIX of The Social Security Act as of November 10, 2016* (2016), available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/Downloads/MedicareMedicaidSummaries2016.pdf (last visited Jan. 31, 2020)

CMS, *CMS Instructions: Requirements for Submitting PDE Data* (June 24, 2005), available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/DrugCoverageClaimsData/Downloads/PDEInstruction_062305.pdf (last visited Jan. 31, 2020)

CMS, *Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services* (Rev. 259, July 12, 2019), available at https://www.cms.gov/media/125221 (last visited Jan. 31, 2020)

CMS, *Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services* (Rev. 151, Nov. 18, 2011), available at

https://www.cms.gov/Medicare/Prevention/PrevntionGenInfo/Downloads/bp102c15.pdf (last visited Jan. 31, 2020)

CMS, *Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage* (Rev. 198, Nov. 6, 2014), available at https://www.cms.gov/media/125201 (last visited Jan. 31, 2020)

CMS, *Medicare Coverage Determination Process*, https://www.cms.gov/Medicare/Coverage/DeterminationProcess (Page Last Modified: 11/19/2019 06:31 PM) (last visited Jan. 31, 2020)

CMS, *Medicare Part D – Direct and Indirect Remuneration (DIR)* (January 19, 2017), available at https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir (last visited Jan. 31, 2020)

CMS, *Medicare Prescription Drug Benefit Manual Chapter 6 – Part D Drugs and Formulary Requirements* (Rev. 18, Jan. 15, 2016), available at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf (last visited Jan. 31, 2020)

CMS, *Off-Label Pharmaceutical Marketing: How to Recognize and Report It*, https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/off-label-marketing-factsheet.pdf (last visited Jan. 31, 2020)

CMS, *Prescription Drug Benefit Manual, Chapter 7 – Medication Therapy Management and Quality Improvement Program* (Rev. 11, Feb. 19, 2010), available at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/Chapter7.pdf (last visited Jan. 31, 2020)

DRUGDEX Evaluation, Darunavir. (https://www.micromedexsolutions.com/home/dispatch, accessed using the search term Darunavir on Nov. 15, 2019)

DRUGDEX Evaluation, Etravirine. (https://www.micromedexsolutions.com/home/dispatch, accessed using the search term Etravirine on Nov. 15, 2019)

FDA, *Guidance for Industry, Labeling for Human Prescription Drug and Biological Products – Implementing the PLR Content and Format Requirements*, (Feb. 2013), available at https://www.fda.gov/media/71836/download (last visited Jan. 31, 2020)

FDA, Intelence Labels, 2008-2014, available at https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=022187 (last visited Jan. 31, 2020)

FDA, Prezista Drug Approval Package, available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2006/021976s000_SprycelTOC.cfm (last visited Jan. 31, 2020)

FDA, Prezista Labels, 2006-2014, available at https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=021976 (last visited Jan. 31, 2020)

Henry J. Kaiser Family Foundation, *Low-Income Assistance under the Medicare Drug Benefit* (2009), available at https://www.kff.org/medicare/fact-sheet/low-income-assistance-under-the-medicare-drug/ (last visited Jan. 31, 2020)

Henry J. Kaiser Family Foundation, *Medicare Advantage* (June 29, 2015), available at http://kff.org/medicare/fact-sheet/medicare-advantage/ (last visited Jan. 31, 2020)

Henry J. Kaiser Family Foundation. *Medicare Chart Book 2005* (June 30, 2005), available at https://www.kff.org/medicare/medicare-chart-book-2005/ (last visited Jan. 31, 2020)

Henry J. Kaiser Family Foundation, *The Medicare Part D Prescription Drug Benef*it (2017). Menlo Park, CA: Henry J. Kaiser Family Foundation, available at http://files.kff.org/attachment/Fact-Sheet-The-Medicare-Part-D-Prescription-Drug-Benefit (last accessed Jan 31, 2020)

Johnson & Johnson, News Release, *U.S. Food and Drug Administration (FDA) Approves Prezista Once-Daily as Part of Combination Therapy for Treatment-Naive Adults with HIV-1* (October 22, 2008). https://johnsonandjohnson.gcs-web.com/news-releases/news-release-details/us-food-and-drug-administration-fda-approves-prezistar-once/ (last visited Jan. 31, 2020)

Johnson & Johnson, News Release, *Once-Daily Prezista (darunavir) for Treatment-Naïve Adults with HIV-1 Receives Approval in the European Union as Part of Combination Therapy* (Feb. 3, 2009) https://johnsonandjohnson.gcs-web.com/news-releases/news-release-details/once-daily-prezistar-darunavir-treatment-naive-adults-hiv-1 (last visited Jan. 31, 2020)

MedPAC, *Report to the Congress: Medicare and the Health Care Delivery System* (June 2015), available at http://www.medpac.gov/docs/default-source/reports/june-2015-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf?sfvrsn=0 (last visited Jan. 31, 2020)

Order re: Defendant's Motion for Summary Judgment, *United States of America, et al., ex rel. Brown v. Celgene Corporation,* No.2:10-cv-03165-RGK-SS, Dkt.369 (C.D. Cal. December 28, 2016)

Office of National AIDS Policy, *National HIV/AIDS Strategy for the United States* (July 2010), http://files.hiv.gov/s3fs-public/nhas.pdf (last visited Jan. 31, 2020)

Office of National AIDS Policy, *National HIV/AIDS Strategy for the United States: Updated to 2020* (July 2015), available at http://files.hiv.gov/s3fs-public/nhas-update.pdf (last visited Jan. 31, 2020)

Q1 Group, LLC, 2020-2006 Medicare Part D Standard Benefit Model Plan Parameters, https://q1medicare.com/PartD-The-MedicarePartDOutlookAllYears.php (last visited Jan. 31, 2020)

Q1 Group, LLC, The Medicare Part D Donut Hole Discount (2011 to 2020), https://q1medicare.com/PartD-MedicarePartD_DonutHole_Discount.php (last visited Jan. 31, 2020)

Rice, Cheri, Director, Medicare Plan Payment Group, Memo to All Part D Plan Sponsors, Subject: PDE Guidance for Post Point-of-Sale Claim Adjustments, July 3, 2013, available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Downloads/PDE-Guidance-Claim-Adjustments.pdf (last visited Jan. 31, 2020)

Richardson, Elizabeth, *Off-Label Drug Promotion,* Health Affairs (June 30, 2016), https://www.healthaffairs.org/do/10.1377/hpb20160630.920075/full/ (last visited January 10, 2020)

West, Notes of Decisions for § 1395w-102, Prescription drug benefits (report generated Jan. 3, 2020)